

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

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|-------------------------------|---|---------------------------------|
| JOHN THUMANN, | : | Case No. 1:20-cv-00125 |
| | : | |
| Plaintiff, | : | |
| | : | District Judge Timothy S. Black |
| v. | : | |
| | : | |
| ALEX M. AZAR II, SECRETARY, | : | |
| U.S. DEPARTMENT OF HEALTH AND | : | |
| HUMAN SERVICES, | : | |
| | : | |
| Defendant. | : | |

ANSWER

Defendant Alex Azar, in his official capacity as Secretary of the United States Department of Health and Human Services, hereby answers the Complaint of John Thumann as follows:

I. SUMMARY

1. This paragraph contains conclusions of law, to which no answer is required.
2. This paragraph contains conclusions of law, to which no answer is required.
3. This paragraph contains conclusions of law, to which no answer is required.
4. The Defendant admits that Plaintiff has been diagnosed with glioblastoma multiforme (GBM). The defendant denies the remaining allegations of this paragraph.

II. JURISDICTION

5. This paragraph contains conclusions of law, to which no answer is required. The Defendant does not contest jurisdiction.
6. This paragraph contains conclusions of law, to which no answer is required. The Defendant does not contest venue.

III. PARTIES

7. The Defendant admits the allegations in this paragraph.

8. The Defendants admits the allegations in this paragraph.

IV. LEGAL BACKGROUND

9. This paragraph contains conclusions of law, to which no answer is required.

10. This paragraph contains conclusions of law, to which no answer is required.

11. This paragraph contains conclusions of law, to which no answer is required.

12. This paragraph contains conclusions of law, to which no answer is required.

V. FACTUAL BACKGROUND

Tumor Treatment Field Therapy (TTFT)

13. The Defendant admits that GBM is a type of brain cancer. The Defendant is without information to admit or deny the remaining allegations in this paragraph.

14. The Defendant admits that TTFT uses alternating electrical fields and has been developed as a treatment for GBM. The Defendant is without information to admit or deny the remaining allegations in this paragraph.

15. The Defendant admits that papers concerning TTFT were published in the Journal of the American Medical Association in 2015 and 2017. The Defendant respectfully refers the Court to these papers located at pages 257-277 of the certified administrative record for a full and accurate statement of their contents. The Defendant is without knowledge to admit or deny the remaining allegations in this paragraph.

16. The Defendant admits that the National Comprehensive Cancer Network assigns TTFT a Category 1 recommendation as a treatment option for newly diagnosed GBM, following

initial maximal debulking surgery (when feasible), chemotherapy, and radiation therapy. The Defendant is without knowledge to admit or deny the remaining allegations in this paragraph.

17. The Defendant admits that Novocure, Inc. is a supplier of equipment that delivers TTFT called the Optune system, that the Optune system is rented on a monthly basis, and that Medicare beneficiaries who are prescribed the Optune system may submit monthly claims for Medicare payment. The Defendant is without knowledge to admit or deny the remaining allegations in this paragraph.

The Medicare Appeals Process

18. The Defendant admits that this paragraph generally describes the Medicare claim appeal process, which is governed by the applicable Medicare laws and regulations.

19. The Defendant admits that Administrative Law Judges and the Medicare Appeals Council are generally required to issue decisions within 90 days, although these deadlines may be waived or extended as provided by the Medicare statute and regulations. 42 U.S.C. § 1395ff(d); 42 C.F.R. §§ 405.1016 and 405.1100. The Defendant is without knowledge to admit or deny the remaining allegations in this paragraph.

Facts Specific to Mr. Thumann

20. The Defendant admits the allegations in this paragraph.

21. The Defendant admits that on August 19, 2019, ALJ Gates issued a decision in ALJ Appeal No. 1-8651191426 authorizing coverage of Plaintiff's TTFT claims from November 2018-January 2019, and that on November 5, 2019, ALJ Bartlett issued a decision in ALJ Appeal No. 3-8757160676 authorizing coverage of Plaintiff's TTFT claims from February 2019-May 2019. The Defendant respectfully refers the Court to pages 10 and 25 of the certified

administrative record for complete and accurate copies of these decisions. The Defendant also admits that he did not appeal either decision, which have become final.

22. The Defendant admits that on September 5, 2019, ALJ MacDougall issued a decision in ALJ Appeal No. 1-8411066311 denying coverage of Plaintiff's TTFT claims from August 2018-October 2018. The Defendant respectfully refers the Court to page 88 of the certified administrative record for a complete and accurate copy of this decision. Plaintiff's characterization of this decision contains conclusions of law, to which no answer is required.

23. The Defendant admits the allegations in this paragraph, except that the Defendant denies that Plaintiff's notice of escalation was filed pursuant to 42 C.F.R. § 405.1016(f) as opposed to 42 C.F.R. § 405.1132.

24. The Defendant admits the allegations in this paragraph.

25. This paragraph contains conclusions of law, to which no answer is required. The Defendant does not contest jurisdiction.

CAUSES OF ACTION

COUNT I

Violation of 42 U.S.C. § 405(g) (contrary to law)

26. The Defendant incorporates by reference its responses to the preceding paragraphs.

27. This paragraph contains conclusions of law, to which no answer is required.

COUNT II

Violation of 5 U.S.C. § 706(1) (unlawfully withheld or unreasonably delayed)

28. The Defendant incorporates by reference its responses to the preceding paragraphs.

29. This paragraph contains conclusions of law, to which no answer is required.

COUNT III

Violation of 5 U.S.C. § 706(2)(A)

(arbitrary and capricious, abuse of discretion, not in accordance with law)

30. The Defendant incorporates by reference its responses to the preceding paragraphs.

31. This paragraph contains conclusions of law, to which no answer is required.

COUNT IV

Violation of 5 U.S.C. § 706(2)(C)

(in excess of statutory jurisdiction, authority, or limitations or short of statutory right)

32. The Defendant incorporates by reference its responses to the preceding paragraphs.

33. This paragraph contains conclusions of law, to which no answer is required.

COUNT V

Violation of 5 U.S.C. § 706(2)(D)

(without observance of procedure required by law)

34. The Defendant incorporates by reference its responses to the preceding paragraphs.

35. This paragraph contains conclusions of law, to which no answer is required.

COUNT VI

Violation of 5 U.S.C. § 706(2)(E)

(not supported by substantial evidence)

36. The Defendant incorporates by reference its responses to the preceding paragraphs.

37. This paragraph contains conclusions of law, to which no answer is required.

VI. PRAYER FOR RELIEF

A-C. Plaintiff's final paragraphs constitute its request for relief to which no answer is required.

JURY DEMAND

Pursuant to 42 U.S.C. § 405(g) (made applicable to Medicare by 42 U.S.C. § 1395ii), review of the administrative decision at issue is by judge only and Plaintiff is not entitled to a trial by jury.

AFFIRMATIVE AND OTHER DEFENSES

1. Plaintiff lacks standing because he has not suffered an injury-in-fact.
2. The Complaint fails to state a claim upon which relief can be granted.
3. The administrative action and decision that is addressed in the Complaint is supported by substantial evidence.
4. The administrative action and decision that is addressed in the Complaint is not arbitrary, capricious, or contrary to law.
5. Collateral estoppel does not apply to non-precedential decisions issued by Administrative Law Judges.
6. The Defendant reserves the right to amend this answer with additional defenses that may become apparent during the course of this litigation and to raise any other matter constituting an avoidance or affirmative defense.
7. The Defendant specifically denies all allegations in the Complaint not otherwise answered herein. In addition, the Defendant denies that Plaintiff is entitled to the relief requested, or to any relief whatsoever.

WHEREFORE, the Defendant respectfully requests that the Court enter judgment in its favor.

Respectfully submitted,

DAVID DEVILLERS
United States Attorney

s/Margaret A. Castro
MARGARET A. CASTRO (0078968)
Assistant United States Attorney
Attorney for Defendant
221 East Fourth Street, Suite 400
Cincinnati, Ohio 45202
Office: (513) 684-3711
Fax: (513) 684-6972
E-mail: Margaret.Castro@usdoj.gov